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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/616,709 | 07/10/2003 | Neil P. Desai | APP01_005_US | 2620 |

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| EXAMINER | |
|---|---|
| TELLER, ROY R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/616,709 | DESAI ET AL. | |
| | Examiner | Art Unit | |
| | ROY TELLER | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-64 and 68-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64 and 68-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/10 has been entered.

Claims 1-64 and 68-88 are under examination.

### Response to Amendments/Arguments

Applicant's arguments and amendments filed 12/16/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-64 and 68-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (USPN 6,399,087) in view of Lundgren et al. (USPN 6,576,245) and Sautou-Miranda et al. (International Journal of Pharmaceutics, 1996, 130, pp-251-255).

The instant invention is drawn to a sterile pharmaceutical composition for parenteral administration of propofol, wherein said composition is stored in a container having a closure wherein said closure is inert to propofol, wherein the composition comprises:

a) about 0.5% to 10% by weight propofol,

b) 3-6% by weight of soybean oil,

c) 0.2-1.0% by weight of egg lecithin,

d) about 2.25% by weight of glycerin,

e) sodium hydroxide,

f) water to 100%,

g) pH between 5.0-8.5,

and when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration measured by HPLC that is at least 93% of the starting concentration of the propofol.

Zhang et al. discloses a sterile pharmaceutical composition for parenteral administration of propofol, wherein the composition comprises :

a) about 1% to 2% by weight propofol,

b) 3-6% by weight of soybean oil,

c) 0.2-1.0% by weight of egg lecithin,

d) about 2.25% by weight of glycerin,

e) sodium hydroxide,

f) water to 100%, and

g) pH between 5.0-7.5.

See, i.e., for example, abstract, column 3, lines 21-22, claims 1-14.

Zhang does not disclose a container having a closure wherein said closure is inert to propofol.

Lundgren et al. discloses a primary package containing low molecular weight peptide-based thrombin inhibitors which package is sealed with a rubber stopper or plunger containing bromobutyl rubber. Lundgren discloses the preferred low molecular weight peptide based thrombin inhibitor be kept in glass vials or syringes. See, i.e., for example, abstract, column 2, lines 1-2, claims 1-5.

Sautou-Miranda et al. discloses propofol stored in glass and polypropylene containers for 30 days with little lose of potency. See, for example, abstract, and page 255.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the composition of Zhang with the beneficial teachings of Lundgren because Lundgren discloses the a low molecular weight package sealed with bromobutyl rubber. The brombutyl rubber would inherently work for a low molecular weight (below 1,000 M.W.) composition such as propofol (M.W. -178.27). Further, Sautou-Miranda disclosure of propofol stored in glass and polypropylene containers for 30 days with little lose of potency beneficially teaches a composition of propofol comprising a container which is inert to propofol. It would be obvious to put any known pharmaceutical composition within that type of sealed container-for well known sterility, stability and transport purposes. Sautou-Miranda disclosure of propofol stored in glass and polypropylene containers for 30 days with little lose of

potency mimics the outcome of the instant claims composition that maintains a propofol concentration that is at least 93% of the starting concentration of propofol.

Applicant's arguments as they pertain to the art rejection above have been carefully considered but were not found persuasive. Applicant contends that the Zhang reference does not disclose any container at all for storing propofol. Applicant further contends that the cited reference fails to disclose claim limitations relating to the container. However, the examiner contends that the Lundgren reference discloses a primary package containing low molecular weight peptide-based thrombin inhibitors which package is sealed with a rubber stopper or plunger containing bromobutyl rubber. Lundgren discloses the preferred low molecular weight peptide based thrombin inhibitor be kept in glass vials or syringes. The brombutyl rubber would inherently work for a low molecular weight (below 1,000 M.W.) composition such as propofol (M.W. -178.27). Further, Sautou-Miranda disclosure of propofol stored in glass and polypropylene containers for 30 days with little lose of potency beneficially teaches a composition of propofol comprising a container which is inert to propofol.

**Conclusion**

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Roy Teller/
Examiner-1654
1/26/11